STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

WASHINGTON STATE BOARD OF PHARMACY
October 25, 2007
Center Point Corporate Park
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CONVENE

Chair Rebecca Hille called the meeting to order at 9:00 a.m. on October 25, 2007.

Board members present:
- Gary Harris, RPh, Vice-Chair
- George Roe, RPh
- Rosemarie Duffy, RN – Public Member
- Dan Connolly, RPh
- Susan Teil-Boyer, RPh
- Vandana Slatter, PharmD

Guests:
- Oscar Chavez, AAG
- Dr. Beth Devine–University of WA
- Diane Schultz – Group Health Cooperative
- Don Downing, University of WA
- Mark Longley, Parata Systems, LLC
- Margaret Gilbert, Senior Staff Attorney - DOH

Laurie Jinkins, Assistant Secretary - DOH

Staff Members Present:
- Steven Saxe, Executive Director (Acting)
- Lisa Salmi, Executive Manager
- Joyce Roper, AAG Advisor
- Tim Fuller, Pharmacist Consultant
- Cathy Williams, Pharmacist Consultant
- Stan Jeppesen, Pharmacist Investigator
- Doreen Beebe, Program Manager
- Karli Bourne, Support Staff

Mission Statement

The mission of the Board of Pharmacy is to achieve the highest standards in the practice of pharmacy, to promote public health and safety. The Board of Pharmacy will educate and effectively communicate with the profession, the public, the Governor, Legislature, the Department of Health.

Vision Statement

The Washington State Board of Pharmacy leads in creating a climate for the patient-focused practice of pharmacy.

Pharmacists inform, educate, consult, manage drug therapy and provide products as an integral part of an accessible, quality-based health care system.

As an outcome, the citizens of Washington State:

- Are well informed about medications;
- Take responsibility for their health;
- Utilize pharmacists and other health care providers appropriately; and
- Experience the highest level of health and wellness.

CONSENT AGENDA

1.1 Pharmacist License Application Approval
- Sarah Becker – Nuclear Pharmacist

1.2 Pharmacy & Other Firm Application Approval

1.3 Pharmacy Technician Application Approval

1.4 Pharmacy Tech Training Program Approval
- Kimberly Williams - Houston Allied Health Careers, Houston TX
- Falicity Johnson – Linn-Benton Community College, OR
- Shari Froberg – Penn Foster Career School, Scranton PA
- Azura Thurston – Costco, Fredericksburg VA
- Sultana Ajani – University of the Sciences, Philadelphia PA
- Leann Wingenback – Medcenter One, Bismarck ND
- Vanessa Lopez – Miami Dade College, Miami FL
- Jillian Bremner – Albertsons, Chicago IL
- Hevi Mohammed – Apollo College, Boise ID
- Samantha Parker – Draughons Junior College, Clarksville TN
- William Hanson – Remington College, Tempe AZ
    - Note: Application for approval of tech training for James Locke was pulled for insufficient documentation of training.

1.5 Collaborative Drug Therapy Agreement Acceptance
- Megan Wheeler – Reliant Rx of Washington, Anticoagulation

1.6 Automated Drug Dispensing Device Acceptance

1.7 Sample Distribution Requests

1.8 Board Minute Approval – September 6, 2007

Items listed under the consent agenda are considered to be routine agency matters and will be approved by a single motion of the Board without separate discussion. Items 1.3, 1.6, and 1.7 were deleted from the agenda. **ACTION:** Motion made by George Roe to approve items 1.1, 1.2, 1.4, and 1.5. Dan Connolly second. **MOTION CARRIED** 7-0.

Suggested amendments to September 6, 2007 Minutes:

Page 2, correct to show that it was Vandana Slatter, not Susan Teil-Boyer who participated on the panel reviewing study plan submitted by pharmacist applicant.
Page 3; correct spelling of "Duffy"
Page 8, strike "is" from paragraph

ACTION: Motion made by Rosemarie Duffy to approve item 1.8 as amended. Susan Teil-Boyer second. **MOTION CARRIED** 7-0.

REPORTS

Acting Executive Director

Steven Saxe *reported:*

- Attendance by Facilities and Services Licensing staff -Institute of Health Care Improvement
    - patient safety officer training
    - adverse event reporting requirements looking at route cause analysis – reporting required by hospital, state correctional facilities, child birth centers, psychiatric hospitals, ambulatory surgery centers
    - Focus: establish patient safety strategic goals; establish a culture and infrastructure that supports patient safety.
- Attended Department of Health Annual Board and Commission Leadership Meeting. One of the topics discussed was the performance audit.
- Hospital association meeting attended which had valuable components related to patient safety
- Attended Ambulatory Surgery Center meeting, in which ESHB 1414 was discussed. ESHB 1414 will address the situation of some ambulatory surgery centers which are not currently licensed coming under the jurisdiction of the Department of Health, Facilities and Services Licensing. More to come on this in the future.
- Mr. Saxe will attend the Citizen Advocacy Center national meeting on October 29, 30, and 31 in Seattle, Washington. One of the seminars will address "Root Cause Analysis Systems" –promoting patient safety and how it works with the regulatory process.
- Mr. Saxe reported on a briefing to Secretary Mary Selecky on deaths due to unintentional poisoning. Data shows a large number of deaths that involve prescription drugs. Also provided the Secretary with an update on the prescription monitoring program and lack of federal funding and the pharmaceutical take back pilot project. Briefed the Board on the basic components of the Department of Health, Health Systems Quality Assurance reorganization, including the 5 offices and the work done under each of these offices. More information will be provided by Assistant Secretary Laurie Jinkins.

Executive Manager

Lisa Salmi *reported:*

- Length of service awards were given to the following staff members at the DOH October 3 Annual Recognition Event: Doreen Beebe, 20 years; Tim Fuller, 15 years; Joe Honda, 15 years.
- Board Chair Rebecca Hille attended the Department of Health Board and Commission Annual Meeting on September 27, which covered the HSQA restructure and the HSQA performance audit, and legislation. Joyce Roper gave a presentation on *Working with Associations*.
- Copies of the performance audit were provided to the Governor as well as members of the Board.
- HSQA has finalized the 2007-09 Strategic Plan. The goals of the plan are:

    1. Improve people's health
    2. Enhance patient safety
    3. Make every resource count
    4. Have an exemplary workforce

5. Deliver exceptional service

Each goal ahs specific objectives and responsibility for each objective has been assigned to an individual.

- Final report of the Workload Standards Study is due to the legislature in December. The focus of this study is on the disciplinary process. Study will assist the Department in determining the resources necessary to perform specific activities for specific types of cases.
- Board member George Roe attended investigators meeting. Investigators reviewed the retail pharmacy inspections checklist to ensure consistency in the inspection process.
- Board member Dan Connolly attended the National Association of Boards of Pharmacy District VII and VIII meeting in Ashland, Oregon, on October 3-6.

Board Member

- Board member Dan Connolly attended the National Association of Boards of Pharmacy (NABP) meeting on Oct 3-6. The American Association of Clinical Pharmacists and the NABP are closely aligning regarding the credentialing of 4th year pharmacy students. They are also working on developing a test for 2nd year pharmacy students to measure performance of different pharmacy schools. This test is expected to be adopted in the next 3-4 years. Patient access to health care was the main focus of the NABP meeting. 41 million persons have no health insurance in USA. NABP is concentrating on quality assurance programs to protect both pharmacies and patients. They are developing uniform standards for all states on quality assurance. The need to develop minimum standards and minimum training/education for pharmacy technicians was also addressed.
- Board member Gary Harris attended Medical Error Dispensing Task Force meeting. Discussion centered on errors and how they come about. Mr. Harris reported he had an opportunity to speak with Governor Gregoire about seeking legislation to fund the prescription monitoring program in this state.
- Board member Susan Teil-Boyer attended the Institute for Health Improvement working on high risk, high alert drugs and adverse events. The IHI website has more information on this. Traditionally, pharmacies track the issues surrounding high risk, high alert drugs/adverse events with incident reporting. The IHI is looking at reporting based on study of trigger events that lead to adverse events rather than continuing to track using only incident reporting.
- Board Chair Rebecca Hille reported on meeting with Secretary Selecky, who complimented the Board of Pharmacy for the hard work on rulemaking which promotes patient safety. The Department of Health reorganization and performance audit was also discussed.

Assistant Attorney General

Joyce Roper *reported:*

- No word yet from the Judge on the Storman's lawsuit case. Tentative trial date of October 2008 has been set for this case.
- Cautioned members not to engage in "reply all" e-mail dialog with other Board members. To comply with the Open Public Meeting Act a *Special Meeting* must be called when a quorum is participating

- Not to identify themselves as Board members if they choose to speak to the legislature on specific bills or other items of interest, unless they have been authorized by a quorum of the board to serve as the board's spokesperson on a particular matter. Should the board authorize lobbying activity, then the board should report this information to DOH, as there are laws requiring reporting of lobbying activities, and DOH will help assure compliance with those laws.
- Ms. Roper summarized her Anti Trust and Working with Associations presentation given at the leadership conference. The presentation highlighted a past anti-trust case where an Oregon Board member was found to be personally liable for damages in excess of one million dollars. This suit caused concern among board and commission members throughout the country. After court appeals and in the final judgment, the board member was no longer named, but that was just because the plaintiff chose to drop the case against the board member. This case exemplifies the reason why Board members should exercise caution when reviewing a competitor's file; participating on peer review committees during the same time they are serving as board members; and using their relationship with the associations, particularly if the activities could be viewed as restricting competitors or competition among those regulated by the board or affiliated businesses or professions. Ms. Roper is working with a task force at Department of Health to develop a rule defining a 60 day supply of medical marijuana based on legislation from last session. The legislation also required the preparation of a report on options for how patients could obtain marijuana for medicinal use.
- Met with Attorney General Rob McKenna on the PH:ARM program. Mr. McKenna has asked Ms. Roper to work with the project to draft another letter to the DEA supporting the waiver for the collection of controlled substances.

Consultant Pharmacist

Tim Fuller *reported:*

- Following the approval of WAC 246-872 Automated Drug Distribution Devices, the Board of Pharmacy directed staff to present the unresolved issue about nurses stocking automated devices to the Nursing Commission. Tim Fuller presented the issue to the Nursing Commission. BJ Noll informed me that the Nursing commission decided that a nurse stocking automated drug distribution devices is within a nurse's scope of practice.
- The volunteer DOH staff, including Lisa Salmi, Jim Doll, and Tim Fuller, will participate in the annual state-wide WASABE exercise in the Spokane area.

Cathy Williams *reported:*

- Working on developing uniform and consistent responses to frequently asked questions.

Program Manager

Doreen Beebe *reported:*

- Visited the Purdy Correctional Facility with pharmacist investigator Jim Lewis. Also attended a Correctional Facility Rules Stakeholders Meeting. Two major concepts discussed: whether or not board has authority to adopt rules regarding correctional facilities which have no pharmacies. The group express strong

concerns that the quality of care should be the same regardless of where an individual is incarcerated.

- The technician training survey was sent out. The survey was sent to 42 pharmacies, and we have received a response from 19 of those pharmacies.
- The proposed rule on delegation of authority to investigate cases remains in the Secretary's office. It has not moved forward. If filed with the Code Reviser's office by November 9th, it will be scheduled for hearing at the December meeting.

PRESENTATIONS

The Intersection of Medication Safety and Human Factor. Dan Connolly introduced Dr. Beth Devine from the University of Washington, Pharmaceutical Outcomes Research & Policy Program. Dr. Devine's presentation focused on medication errors and current trends. She discussed human factors engineering concepts used to identify safety problems and foster improvements in medication safety.

Highlights

- Awareness of medical errors increased since Institute of Medicine published it's report – To Err is Human – concerning medical errors
- Medication errors are preventable adverse drug events
- Most research regarding medication errors has focused on the inpatient setting
- Reporting and identification of medication errors – Only 1 in 20 medication errors are reported due to a number of factors including fear of punitive actions and burden of reporting.
- Aviation Safety Reporting System – provides an example of a non-punitive, voluntary, and anonymous system designed to encourage reporting to prevent accidents.
- Implementation of Technology – can be a help or hindrance in preventing medication errors.
- The Institute for Safe Medication Practices (ISMP) – Key concepts in improving medication safety.
    - Simplify and reduce number of steps and options that may contribute to errors
    - Centralize error-prone processes
    - Standardized Methods
    - Add redundancy – double-check systems and back-up systems
    - Improve access to information
    - Skill, knowledge and rule based performance – used to mitigate errors
- System Engineering Initiative for Patient Safety Model components include: work system (individual, tasks, technology, tools, organization and the environment), process and outcomes. Balanced work systems.

Dr Devine concluded that it is important to educate professional about the importance of improved safety; to implement continuous quality improvement processes; to acknowledge how systems contribute to errors; to acknowledge the role of human factors and to developing a non-punitive reporting system.

Creating a Culture of Safety. Diane Schultz, Medication Safety Manager with Group Health Cooperative gave a presentation on Creating a Culture of Safety. Presentation

focused on Group Health's promotion of anonymous reporting to encourage change and improvement in patient safety.

Highlights:

- GHC implements an on-line reporting tool used to identify trends
  - Types of errors
    - Wrong patient; strength; medication; quantity; sig
  - Medications involved
    - High risk medications; look a like medications; review ISMP Newsletter
  - What stage in the medication use process did the error occur
  - Trends between clinics
  - How was the system involved
- System Improvements
- Just Culture Concepts
  - Errors are inevitable
  - Non-punitive reporting is essential for learning
  - Errors = opportunity for learning and system improvements
  - Most errors result from system problems
  - Staff are accountable for their behaviors
  - Disciplinary Decision Making – outcome-based; rule-based; risk-based. (decision tree)

EXECUTIVE SESSION

The Board adjourned at 12:10 for the Executive Session to discuss personnel issues and pending litigation. The Board reconvened at 1:25 p.m. for presentations and discussion.

PRESENTATION"S Cont'd

Medication Therapy Management (MTM). Don Downing, Clinical Associate Professor, University of Washington, gave a presentation on Medication Therapy Management. MTM services are billable through the new Medicare Part D Prescription Drug program and some employer group insurance programs. Pharmacists who provide this service are a resource to improving the health of patients through medication utilization review and counseling/interaction.

Highlights:

- Role of pharmacists as clinicians – Medicare Part D, employer group insurance programs
- Staffing issues and restructuring workflow to accomplish medication therapy management. (sample workflow, staffing requirements and job description development forms distributed to the Board)
  - Additional technician and/or technology
  - MTM contractual pharmacist
- Medication Therapy Management – patient not medication focused system.
  - Services currently being provided by pharmacists without compensation. Examples: intervention – drug interactions, brand generic switches and drug adherence, etc.
- Mirixa™ – Commonly used system for documenting/accounting/.billing for medication therapy services. Thirty minute session = $60.

- Cost savings to pharmacy resulting from MTM services

Technology Demonstration. Mark Longely, representing Parata Systems, LLC will provide an overview of the technology, functionality and application of an automated will-call system. The presentation was informative only; no Board endorsement or approval was intended or given.

DISCUSSION

Mandatory Reporting Rules. Margaret Gilbert, Senior Staff Attorney for the Department of Health presented a summary of rule making activities taking place to implement Substitute House Bill 2974 Section 2. Ms. Gilbert discussed how the law and subsequent rule may impact the pharmacy profession and how the Board may get involved in the rule making process.

Governor Gregoire has directed the Department of Health to implement mandatory rules reporting by March 2008. The Governor noted that mandatory reporting is one of the best ways disciplinary authorities can learn about patients at risk.

Once the new rules are adopted, the pharmacy rule WAC 246-867-030 --Reporting and freedom from liability rules -- will be examined for possible revision.

Ms. Gilbert advised the Board that the Mandatory Reporting rules will impact pharmacy program license holders and may have ramification on the disciplinary work done by the Board.

What changed with the enactment of SHB 2974?

- Rule making authority changes from the disciplinary authorities to the secretary of health.
- Reporting to the disciplinary authority by individuals and entities, other than patients, is mandatory.

What did not change?

- Reports include convictions, determinations, or finding that a license holder has committed an act which constitutes unprofessional conduct, OR reports from impaired provider programs indicating a practitioner may not be able to practice safely due to a physical or mental condition.
- Immunity from liability for making reports
- Obligation to self-report – failure to report in 30 days is grounds for disciplinary action.

Ms. Gilbert summarized the rule making activities that have taken place since August in drafting rules. She advised the Board that the Department of Health will be working on a website where updates can be accessed and comments may be posted.

Update: DOH – Mandatory Report Webpage located at:
http://www.doh.wa.gov/hsqa/hpqa/HPQAManRep/HPQAManRep.htm

Federal Drug Administration Requests for Comments Regarding Behind the Counter Medications. The FDA is requesting comments on expanding the availability of certain drugs for purchase by patients from behind the pharmacy counter. Comments are due to the FDA by November 28, 2007. A comment was made to change the term "behind the counter" to "pharmacist provided" or "pharmacist only" medications. The board agreed it would be cost effective and provide greater patient access to have pharmacist provided drugs; however, there needs to be controls and oversight in place to ensure the pharmacist has adequate knowledge regarding the drugs being dispensed. **ACTION:** George Roe motioned for the Board to submit comments to the FDA in regards to expanding the availability of behind the counter medications. Vandana Slatter second. **MOTION CARRIED** 6-0. Gary Harris will draft the letter on behalf of the Board recommending the term "pharmacist only" be used and controls are established to ensure that a pharmacist has adequate knowledge. The letter will be sent to Tim Fuller and Joyce Roper for finalization.

Rod Shafer, CEO of the Washington State Pharmacy Association, suggested that the Board's response/comments should specifically address the issues (25 questions) listed in the FDA's notice.

Joyce Roper added that "behind the counter/pharmacist only" issue might offer an option during an emergency event.

Pharmacist to Technician Ratio. Long-term care pharmacy Northwest Health Systems (NHS) presented its request for an exception to the pharmacist to pharmacy technician ratio of 1:3. The pharmacy's service plan asks that the ratio be increased to 1:5 to free pharmacist from performing clerical duties or non-discretionary tasks that can be performed by other staff. Additional duties of the pharmacists include training nursing staff in long-term care facilities; medication therapy management; changes in pharmacy practices and technology; and other specialty services. Challenges include turnover of staff pharmacists.

John Prete, Director of Pharmacy at Northwest Health Systems suggested that the Board may need to consider amending the rules that establish the 1:3 ratio to reflect the changes and demands in the practice of pharmacy today. NHS currently processes approximately 1,300 prescriptions per day.

Rosemarie Duffy expressed concerns regarding the proposal which stated that a pharmacist who is off-site, due to illnesses or other emergent causes would be counted in the pharmacist to technician ratio. This could theoretically result in 1 pharmacist to 10 technicians.

In considering NHS's proposal against the standards established in WAC 246-901-140 -- Pharmacy service plan, members of the Board and Joyce Roper had concerns whether NHS' proposal would provide appropriate oversight of the pharmacy technicians.

ACTION: George Roe moved to postpone the decision until the Board has received additional information. Rosemarie Duffy suggested amending the motion to include consideration for future rule making. Susan Teil-Boyer second. **MOTION CARRIED**. 6-0.

Dan Connolly shared with the Board that the top of ratios was discussed at the recent National Association of Boards of Pharmacy meeting. Many states are looking at this issue and considering adjusting ratios for hospitals and long-term care practice sites.

The Board requests that Board staff research ratio standards held by other states and provide for the Board's consideration prior to entering a decision on NHS's proposal.

Correspondence – The Board had no discussion regarding the following correspondence.

- NABP – regarding computer based test of English as Foreign Language.
- PH:ARM project update. Pharmaceutical Household Waste – A Return Mechanism.
- Article: *Hospitals add remote monitoring services to improve ICU's*
- NABP – North American Pharmacist Licensure Exam (NAPLEX) reinstated.
- Letter requesting the Board to broaden scope of correctional facilities rule making process.

  Note: Following the meeting the Board held a rule writing workshop to establish standards for pharmacies located in correctional facilities. At the workshop the Board acknowledged that the *Preproposal Statement of Inquiry* announcing the Board's intent to develop rules was written broadly enough to expand the rule development to address the practice of pharmacy for all correctional facilities.

OPEN FORUM

Mr. Steve Sarich, Executive Director of CannaCare presented a letter to the Board regarding the Board's authority to reschedule marijuana. Mr. John Worthington, who accompanied Mr. Sarich, also shared with the Board his concerns regarding the scheduling of medical marijuana.

PRESENTATION OF AGREED ORDERS

Business Meeting Adjourned

There being no further business, the Board adjourned at 4:40 p.m. The Board of Pharmacy will meet again on December 13, 2007 in Kent, Washington.

Respectfully Submitted by:

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Karli Bourne/Doreen Beebe – DOH Staff

Approved on December 13, 2007

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Rebecca Hille, Chair
Board of Pharmacy